



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PESTICIDE
PROGRAMS

February 15, 2022

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Counsel for Sharda Cropchem Ltd.

**Re: Petition of Bayer to Deny the Application for Registration of
Prothioconazole Technical Product**

Dear Ms. Szmuszkovicz and Mr. Wagner:

The Environmental Protection Agency (“EPA” or “the Agency”) received Bayer CropScience’s (“Bayer”) petition to deny Sharda Cropchem Ltd.’s (“Sharda”) follow-on application for Prothioconazole Technical Product (“Technical” PC Code 113961) on May 11, 2021. Sharda did not respond to the petition. The Agency requested additional briefing from Bayer and Sharda on August 24, 2021, and received a response from Bayer on September 7, 2021. and a response from Sharda on September 13, 2021. Bayer’s response included an updated data matrix list whereby it removed two studies it originally claimed Sharda owed compensation for. *See* Bayer response letter, September 7, 2021. Sharda’s response stated that it would agree to cite and offer to pay for five of the 29 remaining data or other items at issue. However, Sharda argued that beyond the five additional items they committed to making an offer to pay for, Bayer’s petition lacked merit and should be dismissed. Specifically, Sharda asserted that “Bayer ignores the clear distinction that EPA has repeatedly recognized between data that are required to satisfy data requirements which may be subject to compensation under the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA), and data that EPA may review for various scientific regulatory purposes which does not trigger a compensation obligation.” *See* Sharda response, September 14, 2021.¹

EPA has reviewed the submitted petition and response and has determined that Sharda would need to cite some, but not all, of the studies listed in the petition. The Agency believes that this petition does have merit and the failure to cite these studies would be grounds for canceling Sharda’s registration under 40 C.F.R. § 152.99 (c)(3). Therefore, if Sharda adds the studies listed below to their data matrix, makes an offer to pay for these studies, and submits documentation to EPA, the Agency will consider this petition to be resolved.

STUDIES THAT NEED TO BE CITED

- | | |
|----------|---|
| 50489203 | This honeybee study meets the requirements under 40 CFR 158, the DCI, and SS-1254. Sharda has not met this requirement. |
| 46923601 | Under Guideline 870.3700, this soybean study was listed as supplemental, but study is listed as “acceptable non-guideline” in OPPIN Query and meets the data requirement [870.3700]. Sharda has not met this requirement. ² |
| 47626901 | Under Guideline 850.1300, this chronic freshwater invertebrate tox for prothio-desthio degradate study was listed as supplemental by EFED, but was considered to meet the data requirement at [850.1735]. Sharda has not met this requirement. |
| 47002601 | Under Guideline 875.2100, this foliar residues on various crops study was used in both occupational residential exposure assessments for new use on rapeseed subgroup (20A) and dislodgeable foliar residue, and must be cited. Sharda has not met this requirement. ³ |
| 48938301 | Under Guideline 860.1340, this storage stability study meets registration requirements for residue chemistry data, and should be cited. Sharda has not met this requirement. |

¹ EPA notes that on August 24, 2021 email correspondence, Bayer's representative asserted that Sharda's September 14, 2021 response, titled " RE: Petition of Bayer to Deny the Application for Registration of Prothioconazole Technical Product [IWOV-PaleyDocs.FID659370]" was not received within the 60-day deadline prescribed by EPA and therefore should not be considered. While Sharda’s counsel argues that Sharda's September 14, 2021 letter and corresponding exhibits were submitted in response to EPA's additional request for briefing and were received within the 14-day timeframe provided, the Agency’s request for supplemental briefing was narrow in scope and did not expand to responses to Bayer’s original petition. Therefore, EPA has declined to consider Sharda’s September 14, 2021 response on the grounds that it was untimely.

² While Sharda has stated they will make an offer to pay for this study, until EPA receives a copy of such, Sharda's obligations under 40 CFR Part 152 have not yet been met.

³ While Sharda has stated they will make an offer to pay for this study, until EPA receives a copy of such, Sharda's obligations under 40 CFR Part 152 have not yet been met.

- 47277008 Under Guideline 860.1380, this seed treatment assessment includes the magnitude of residue in or on wheat. These uses are on the label, and should be cited. Sharda has not met this requirement.⁴
- 48516202 Under Guideline 860.1380, this corn seed treatment study is included on the product label. This study bridges from foliar to seed treatment on the crop group 15 crops, and should be cited. Sharda has not met this requirement.
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- 48516205 Under Guideline 860.1380, this corn seed treatment study is included on the product label. This study bridges from foliar to seed treatment on the crop group 15 crops, and should be cited. Sharda has not met this requirement.
- 49281501 Under Guideline 860.1380, this magnitude of residues in and on corn study that measures formulation for in-furrow application is required. Sharda has not met this requirement.
- 48024904 Under Guideline 860.1500, this potato EU seed treatment field trials study is required. Sharda has not met this requirement.

STUDIES THAT DO NOT NEED TO BE CITED

- 50489204 This Tier 2 tunnel study was submitting in response to the DCI but was not reviewed by EFED. Data was not reviewed by EFED and therefore not required. Guideline 850.3020 has been satisfied with 46246046, 46246048, 50489202, and additional pollinator studies are 50633903 and 50633902.
- 50489205 This Tier 2 colony feeding study was submitting in response to the DCI but was not reviewed by EFED. Data was not reviewed by EFED and therefore not required. Guideline 850.3020 has been satisfied with 46246046, 46246048, 50489202, and additional pollinator studies are 50633903 and 50633902.
- 50521801 This bumble bee study is not only listed as supplemental but was conducted on bumblebees not honeybees. This study cannot be considered required by EPA's Environmental Fate and Effects Division (EFED) or the DCI because all pollinator studies were to be run on only honeybees.

⁴ While Sharda has stated they will make an offer to pay for this study, until EPA receives a copy of such, Sharda's obligations under 40 CFR Part 152 have not yet been met.

- 50521802 This bumble bee study is not only listed as supplemental but was conducted on bumblebees not honeybees. This study cannot be considered required by EPA's Environmental Fate and Effects Division (EFED) or the DCI because all pollinator studies were to be run on only honeybees.
- 50521803 This Tier 2 tunnel study was submitting in response to the DCI but was not reviewed by EFED. This voluntary submission data was not reviewed by EFED and therefore not required as earlier data has satisfied the DCI.
- 50546501 This chronic testing protocols study is not required.
- 48024803 Under Guideline 860.1380 and HED and EFED assessments, this drinking water assessment study is from use on rice, which is a use not listed on the label and not required.
- 46841000 Under Guideline 860.1500, this is a Directions for Use study. This study and all Direction for Use studies are not studies EPA would expect to be cited on any data matrix. These are transmittal documents, and have not been reviewed, therefore they are not cited and not required. All data submitted to support of an application are formatted in accordance with guidance in Pesticide Registration Number 11-3 (formerly 86-5). A submission consist of all the documents submitted to the agency and should be accompanied by a transmittal document. The transmittal document describes basic information about the submission (i.e. applicant name, address, list of documents in submission, list of data and guideline numbers).
- 47005800 Under Guideline 860.1500, this is a Directions for Use study. This study and all Direction for Use studies are not studies EPA would expect to be cited on any data matrix. These are transmittal documents, and have not been reviewed, therefore they are not cited and not required. All data submitted to support of an application are formatted in accordance with guidance in Pesticide Registration Number 11-3 (formerly 86-5). A submission consist of all the documents submitted to the agency and should be accompanied by a transmittal document. The transmittal document describes basic information about the submission (i.e. applicant name, address, list of documents in submission, list of data and guideline numbers).
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- 47521900 Under Guideline 860.1500, this is a Directions for Use study. This study and all Direction for Use studies are not studies EPA would expect to be cited on any data matrix. These are transmittal documents, and have not been reviewed, therefore they are not cited and not required. All data submitted to support of an application are formatted in accordance with guidance in Pesticide Registration Number 11-3 (formerly 86-5). A submission consist of all the documents submitted to the agency and should be accompanied by a transmittal document. The transmittal document describes basic information about the submission (i.e. applicant name, address, list of documents in submission, list of data and guideline numbers).
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- 49516200 Under Guideline 860.1500, this is a Directions for Use study. This study and all Direction for Use studies are not studies EPA would expect to be cited on any data matrix. These are transmittal documents, and have not been reviewed, therefore they are not cited and not required. All data submitted to support of an application are formatted in accordance with guidance in Pesticide Registration Number 11-3 (formerly 86-5). A submission consist of all the documents submitted to the agency and should be accompanied by a transmittal document. The transmittal document describes basic information about the submission (i.e. applicant name, address, list of documents in submission, list of data and guideline numbers).
- 49531300 Under Guideline 860.1500, this is a Directions for Use study. This study and all Direction for Use studies are not studies EPA would expect to be cited on any data matrix. These are transmittal documents, and have not been reviewed, therefore they are not cited and not required. All data submitted to support of an application are formatted in accordance with guidance in Pesticide Registration Number 11-3 (formerly 86-5). A submission consist of all the documents submitted to the agency

and should be accompanied by a transmittal document. The transmittal document describes basic information about the submission (i.e. applicant name, address, list of documents in submission, list of data and guideline numbers).

49533300 Under Guideline 860.1500, this is a Directions for Use study. This study and all Direction for Use studies are not studies EPA would expect to be cited on any data matrix. These are transmittal documents, and have not been reviewed, therefore they are not cited and not required. All data submitted to support of an application are formatted in accordance with guidance in Pesticide Registration Number 11-3 (formerly 86-5). A submission consist of all the documents submitted to the agency and should be accompanied by a transmittal document. The transmittal document describes basic information about the submission (i.e. applicant name, address, list of documents in submission, list of data and guideline numbers).

Please email the requested documentation to the contacts listed below within 15 business days of receiving this letter. If you cannot provide adequate documentation, you may withdraw the pending product applications and request voluntary cancellation of the registered products.

If you have any questions regarding this matter, they should be directed to me in writing at stoner.nora@epa.gov.

Sincerely,
**NORA
STONER**

Digitally signed by
NORA STONER
Date: 2022.02.15
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Nora Stoner
Office of Chemical Safety and Pollution Prevention
Office of Program Support
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cc. Allison Payne (payne.allison@epa.gov) (OGC/PTSLO)
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